



Innovation Regulatory Subcategory Lead (m/w/d) Bezahlung nach Chemietarif

Your future employer is a successful life sciences company worldwide. With over 100,000 employees, this global group is specialized in the research and development, manufacturing and marketing of pharmaceutical products in the prescription market.

For this very international and high-quality oriented Client, we are looking for in Frankfurt:

Innovation Regulatory Subcategory Lead (m/w/d) Bezahlung nach Chemietarif

Your future tasks and responsibilities:

Opportunity

- The Innovation Regulatory Subcategory Lead will be in charge of the strategic and operational regulatory affairs activities for a portfolio of a major global brand including multi-regional pipeline development and marketed products of the category.
- The Innovation Regulatory Lead will be responsible for developing and delivering innovative, breakthrough global regulatory strategies for product development and approval, in alignment with the category global business strategy.

Key Accountabilities

- Regulatory (Sub-)Category Leadership
- As a full member of the Category and Brand team, contributes to provide regulatory insights to help drive and shape the Category and Brand strategy - Be the key global regulatory expert and go-to contact



for the respective INNs as per sub-category

-Substantially drive the pipeline development strategies in alignment with the business strategy including early stage operational responsibilities

- Contribute to the development of the regulatory strategy for the respective portfolio, working collaboratively with the global regulatory office community and cross functional teams to create project plans that identify opportunities, regulatory risks and mitigation strategies
- Provides regulatory strategy and intelligence for due diligence and business development initiatives
- Proposes the strategy for HA Interaction and attend HA meetings as required ensuring that all projects have clearly defined regulatory paths to deliver and milestones are met leading to successful filings and approvals

Product/projects regulatory management

- As a regulatory portfolio owner, is accountable for the development of the global regulatory strategies for projects/products within the assigned portfolio, in close collaboration with Regional Scientific Affairs teams.
- Be a strategic partner for and work closely with the Scientific Innovation team for their sub-category & align with them on prioritized innovation projects
- Is accountable of the coordination of the preparation and on-time delivery of compliant submissions to Regulatory Agencies and for managing responses to Regulatory Agencies questions
- Is accountable of the follow up of the implementation of the global strategy with regulatory affairs in affiliates.
- Ensures timely execution of agreed regulatory milestones for the development projects
- Is accountable of the coordination of the preparation and on-time delivery of compliant submissions to Regulatory Agencies and for managing responses to Regulatory Agencies questions
- Is accountable of the follow up of the implementation of the global strategy with regulatory affairs in affiliates.
- Ensures timely execution of agreed regulatory milestones for the development projects
- Develop submission strategy and participate in the organization of scientific advice meeting with the Health Authorities

Your career profile:

- Minimum MS; Pharm D, MD, PhD or equivalent preferred
- Minimum 10 years in Regulatory Affairs, including leadership roles, and experience managing, and leading global team required.
- Proven track record in development and execution of regulatory strategies, preferably with significant experience in OTC medicinal products, medical devices and food supplements including pipeline development, due diligences, drug development
- Extensive knowledge of laws and regulations affecting the global healthcare industry
- Recognized expert in managing global matrix teams and partnering with cross functional teams at a highly strategic level.
- Experience living in different global regions/ countries desirable
- Fluency in English, verbally as well as in writing, preferably also in a second language together with a sense for diverse cultures
- Strategic thinking, creativity and problem-solving
- Strong analytical thinking, action planning and organizing
- Team spirit, persuasiveness & influence, highly collaborative with all cross functional partners
- Ability to be flexible and adapt quickly to changing strategies and priorities



- Excellent communicator both written and verbal, especially in groups, preparing and delivering presentations

Your professional future:

- Look forward to a future-proof job with performance-related remuneration and attractive working conditions.
- A modern work environment with a progressive employer with economic stability welcomes you.
- You will be carefully and well organized in your department by a specially assigned colleague.

Gerne stehen wir Ihnen unter Angabe der folgenden Referenznummer für Rückfragen zur Verfügung.

Reference-Number: 405670A18170

Your contact:

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